

CLAIMS

1. An edible oral mucosal patch comprising a fentanyl compound, a semi-synthetic water-insoluble polymer compound, a semi-synthetic water-soluble polymer compound, a synthetic water-soluble polymer compound, a water-soluble polyhydric alcohol and a pH-adjusting agent.

2. The edible oral mucosal patch according to claim 1, wherein the fentanyl compound is fentanyl citrate.

3. The edible oral mucosal patch according to claim 1, which is formed of a single-layer, and wherein the pH of an aqueous solution prepared by mixing 2 parts by weight of the oral mucosal patch with 98 parts by weight of water, followed by dissolving the oral mucosal patch is 4.0 to 8.0.

4. The edible oral mucosal patch according to claim 1, which comprises a non-disintegrating support layer containing of a semi-synthetic water-insoluble polymer compound, a synthetic water-soluble polymer compound and a water-soluble polyhydric alcohol; and a disintegrating drug layer containing a fentanyl compound, a semi-synthetic water-soluble polymer compound, a synthetic water-soluble polymer compound, a water-soluble polyhydric alcohol and a pH-adjusting agent.

5. The edible oral mucosal patch according to claim 4, wherein the fentanyl compound is fentanyl citrate.

6. The edible oral mucosal patch according to claim 4, wherein the pH of an aqueous solution prepared by mixing 2 parts by weight of the oral mucosal patch with 98 parts by

weight of water, followed by dissolving the drug layer is 4.0 to 8.0.

7. The edible oral mucosal patch according to claim 1, which comprises a disintegrating support layer containing a semi-synthetic water-insoluble polymer compound, a semi-synthetic water-soluble polymer compound, a water-soluble polyhydric alcohol and a pH-adjusting agent; and a disintegrating drug layer containing a fentanyl compound, a semi-synthetic water-soluble polymer compound, a synthetic water-soluble polymer compound and a water-soluble polyhydric alcohol.

8. The edible oral mucosal patch according to claim 7, wherein a dissolution-rate ratio of the drug layer to the support layer in the second fluid of the disintegration test method defined in the Japanese Pharmacopoeia falls within the range of 5:1 to 1:5.

9. The edible oral mucosal patch according to claim 7, wherein a dissolution-rate ratio of the drug layer to the support layer in the second fluid of the disintegration test method defined in the Japanese Pharmacopoeia falls within the range of 3:1 to 1:3.

10. The edible oral mucosal patch according to claim 7, wherein the support layer and the drug layer are multilayered by lamination.

11. The edible oral mucosal patch according to claim 7, wherein the fentanyl compound is fentanyl citrate.

12. The edible oral mucosal patch according to claim 7, wherein

the pH of an aqueous solution prepared by mixing 2 parts by weight of the oral mucosal patch with 98 parts by weight of water, followed by dissolving at least the drug layer is 4.0 to 8.0.

13. The edible oral mucosal patch according to claim 1, wherein

the semi-synthetic water-insoluble polymer compound is at least one selected from the group consisting of ethyl cellulose and hydroxypropylmethyl cellulose phthalate;

the semi-synthetic water-soluble polymer compound is at least one selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, sodium carboxymethyl cellulose and sodium alginate;

the synthetic water-soluble polymer compound is at least one selected from the group consisting of carboxyvinyl polymer, polyvinyl pyrrolidone, polyvinyl alcohol and sodium polyacrylate;

the water-soluble polyhydric alcohol is at least one selected from the group consisting of polyethylene glycol, propylene glycol, glycerin, D-sorbitol, maltitol and xylitol; and

the pH-adjusting agent is at least one selected from the group consisting of sodium hydroxide, sodium acetate trihydrate, anhydrous sodium hydrogencarbonate, anhydrous

disodium hydrogenphosphate, disodium hydrogenphosphate
dodecahydrate, trisodium phosphate dodecahydrate and calcium
lactate pentahydrate.